

## REMARKS

Applicants submit this Amendment in response to the Office Action mailed on April 28, 1999. The Office Action rejects Claims 1-20 under the judicially created doctrine of obviousness-type double patenting, rejects Claim 4 under 35 U.S.C. §112 and rejects Claims 1-20 under 35 U.S.C. §102 and §103. Applicants have amended Claims 1, 4, 9 and 12 as well as added new Claims 21-22. In view of the amendments and for the reasons set forth below, Applicants respectfully request reconsideration of now pending Claims 1-22.

At the outset, the Patent Office rejects Claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-30 of U.S. Patent No. 5,661,123 ("*Stalker et al*"). In this regard, the Patent Office recognizes that the conflicting claims are not identical and indeed introduce different use and various different concentrations of ingredients. Nonetheless, the Patent Office asserts that the claims are not patentably distinct from the patented claims, because they fail to purportedly add a distinctive limitation to the claims of *Stalker et al*.

Applicants respectfully traverse the Patent Office's obviousness-type double patenting rejections. First, Applicants respectfully submit that the Patent Office has failed to provide any rationale for the pending claims of this application being rejected over the claims of *Stalker et al*. Instead, the Patent Office simply states that the pending claims "fail to add a distinctive limitation to the claims of" *Stalker et al*. Applicants respectfully submit that this general statement does not satisfy the Patent Office's initial burden.

Second, Applicants respectfully submit the pending claims do add distinctive limitations. Unlike the claimed invention, *Stalker et al* provides a nutritional composition designed for patients with increased protein needs. Specifically, the claimed enteral composition includes a

protein source constituting approximately 22% to 27% of the caloric distribution of the composition. Moreover, *Stalker et al*, at best, teaches the use of a composition with a caloric density of 1.0 kcal per mL, which the Patent Office recognized on page 9 of the Office Action.

In contrast thereto, the presently claimed invention provides a product that is specifically directed to meet the nutritional needs of metabolically stressed patients without elevated protein levels or excess fluid. To this end, the present invention provides calorically dense nutritional support in the form of an elemental diet while at the same time providing a moderate NPC/gN ratio. Indeed, each of the independent claims requires the use of a protein source comprising approximately 15% to 20% of the calorie distribution of the composition. Moreover, each of the independent claims requires that the enteral composition have a caloric density of at least 1.4 kcal/mL. Thus, Applicants respectfully submit that claimed invention does add distinctive limitations over the claims of *Stalker et al*.

Next, the Patent Office rejects Claim 4 under 35 U.S.C. §112, second paragraph, as being indefinite and vague for failing to particularly point and distinctly claim the subject matter that Applicants regard as the invention. Applicants have amended Claim 4 as well as Claim 12 to require that the enteral composition include 100% of U.S. RDA of vitamins and minerals in approximately 1500 kcal. Support for this amendment can be found, for example, on page 9, line 24 - page 10, line 2. Likewise, Applicants have amended page 4 of the specification to insert similar language.

The Patent Office then rejects the pending claims based on a multitude of cited references. First, the Patent Office rejects Claims 1-7, 9-13, 15 and 17-20 under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5, 504,072 ("*Schmidl et al*"). Second, the Patent Office rejects Claims 1-20 under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,480,872 ("*Cope et*

*al '872*"). For each of these rejections, Applicants respectfully note that the Patent Office has appeared to misconstrue the scope of these references.

Applicants respectfully submit that neither *Schmidl et al* nor *Cope et al '872* anticipate the claimed invention. Each of the independent claims specifically requires that the enteral composition have a caloric density of at least 1.4 kcal/mL. In contrast to the claimed invention, *Schmidl et al*, at best, teaches the use of a liquid composition having a caloric content of one calorie per milliliter (see col. 7, lines 54-57). Likewise, the nutritional product in *Cope et al '872* has a caloric density of 1.2 to 1.35 cal/mL (col. 5, lines 16-18).

Moreover, each of the independent claims requires that the protein source consists essentially of partially hydrolyzed protein. Unlike the claimed invention, *Schmidl et al* teaches the use of intact protein along with protein hydrolysate. Whereas, *Cope '872* actually teaches away from using essentially partially hydrolyzed protein and clearly requires the presence of intact protein (see col. 9, lines 21-26.) Accordingly, each of these references fails to teach all the features of the claimed invention.

Next, the Patent Office rejects Claims 1-20 under 35 U.S.C. §102 as being anticipated by U.S. patent No. 5,714,472 ("*Gray et al*"). Applicants respectfully submit that *Gray et al* likewise fails to teach all the features of the claimed invention. As noted above, the claimed invention provides a product that is specifically directed to meet the nutritional needs of metabolically stressed patients without elevated protein levels or excess fluid. Unlike prior formulations, the claimed invention provides calorically dense nutritional support in the form of an elemental diet while at the same time providing a moderate NPC/gN ratio.

Applicants respectfully submit that *Gray et al* fails to teach the claimed invention. For instance, in contrast to the claimed invention, *Gray et al* specifically teaches one of skill in the

art to make an enteral formulation having a high protein content of at least 22% of the calories of the product (see col. 3, lines 62-65). Unlike the claimed invention, *Gray et al* teaches that the total non-protein calories per gram of nitrogen is less than or equal to 70:1 (see col. 7, lines 21-23). Further, *Gray et al* fails to teach a number of features of the dependent claims (i.e. Claim 7, 14, 15, 19).

The Patent Office then rejects Claims 1-3, 5 and 7-16 under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 5,700,782 ("*Cope et al '782*"). Similar to the other references, Applicants respectfully submit that *Cope et al '782* fails to teach all the features of the now claimed invention. Each of the independent claims requires the use of partially hydrolyzed whey protein. In contrast to the claimed invention, *Cope et al '782* teaches one of skill in the art that the protein source for the nutritional product is a combination of a soy protein isolate and sodium caseinate. Indeed, by not rejecting dependent Claim 6, the Patent Office has agreed that *Cope et al* does not teach this feature. Still further, Applicants have found no teaching of providing a calorically dense product while at the same time providing a moderate NPC/gN ratio, as claimed in this application, as well as other features of the dependent claims.

Lastly, the Patent Office rejects Claims 1-20 under 35 U.S.C. §103 as being unpatentable over a combination of nine references. Specifically, the Patent Office rejects Claims 1-20 as being unpatentable over a *Traumacal* brochure, U.S. Patent No. 5,166,189 and *Stalker et al*, as applied to Claims 1-20 above, and in view of *Schmidl et al*, *Cope et al '872*, *Gray et al*, *Cope et al '782*, U.S. Patent No. 4,427,658 ("*Maubois et al*"), and *Granger et al*. After identifying the purported teachings of each of the cited references, the Patent Office asserts that using the teachings of *Gray et al* or *Cope et al* or *Stalker et al* and *Maubois et al* to further modify the *Traumacal* formulation to provide an improved enteral product that meets the specific nutritional

requirements of metabolically stressed patients would have been obvious to one of ordinary skill in the art. In addition, the Patent Office asserts that utilizing the teaching of *Schmidl et al*, *Trimbo* and *Maubois et al* to further modify *Traumacal* formulation to provide an improved enteral product that meets the specific nutritional requirements of metabolically stressed patients would have been obvious to one of ordinary skill in the art. Lastly, the Patent Office asserts that it would have obvious to one of ordinary skill in the art to use the teachings of *Schmidl et al* and further modify the nutritional formulation of *Cope et al* '872 to provide an improved enteral product that meets the specific nutritional requirements of metabolically stressed patients.

At the outset, Applicants respectfully submit that the Patent Office has simply failed to set out a *prima facie* case of obviousness. In considering obviousness, the critical inquiry is whether something in the prior art as a whole suggests the desirability, and thus the obviousness, of making a combination. *In re Newell*, 891 F.2d 899, 901-02 (Fed. Cir. 1989). Of course, the Patent Office "cannot pick and choose among the individual elements of assorted prior art references to create the claimed invention." *Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F.2d 878, 887 (Fed. Cir. 1988). In fact, unless the prior art suggests the desirability of a modification, the mere fact that the prior art could be modified does not make the modification obvious. *In re Gordon et al*, 733 F.2d 900, 902 (Fed. Cir. 1984).

Here, the Patent Office has failed to demonstrate any motivation to combine the various cited references together that would render the claimed invention obvious. As noted above, the Patent Office relies on a combination of nine references in rejecting the pending claims. In doing so, Applicants respectfully submit that the Patent Office merely sets forth the individual components of the claimed invention that are found within these references and then relies solely on the purported teachings of the *Granger et al* reference as bases for combining all such

references together. The Patent Office fails to identify the motivation or suggestion in the various cited references that would lead one of skill in the art to combine such references in an attempt to yield Applicants' invention. Again, the obviousness inquiry "is not whether such element exists in the prior art, but whether the prior art made obvious to the invention as a whole for which patentability is claimed." *Harness International, Inc. v. Simplimatic Engineering Co.*, 891 F.2d 1100 (Fed. Cir. 1987).

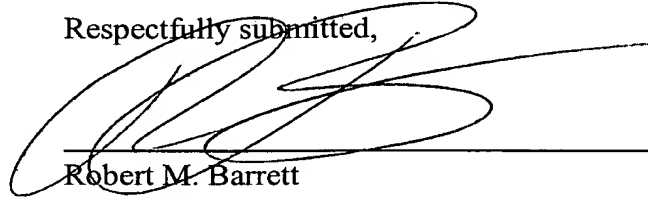
Moreover, Applicants respectfully submit that the primary reference, which Applicants understand to be the *Traumacal* brochure, fails to provide the teachings as suggested by the Patent Office. The Patent Office appears to find that the only feature missing from the *Traumacal* formulation is the incorporation of hydrolyzed whey protein.

However, the reference fails to meet a vast number of the claimed features. For instance, in contrast to the claimed invention, the *Traumacal* formulation incorporates a higher protein content, namely a protein content of at least 22% of the calories of the total composition. The *Traumacal* formulation also does not teach the moderately claimed ratio of non-protein calories per gram nitrogen, the claimed vitamin profile or the use of beta-carotene. Still further, the *Traumacal* formulation only meets the U.S. RDA of vitamins and minerals in 3000 kcal (2000 mL). Accordingly, the primary reference fails to teach many essential features of the claimed invention.

Still further, for the reasons detailed above, Applicants respectfully submit that the secondary references fail to remedy the deficiencies of the primary reference. As noted above, each of the main cited references relied upon by the Patent Office fail to teach various features of the claimed invention. Thus, Applicants respectfully submit that the combination set forth by the Patent Office fails to render the claimed invention obvious.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance. Hence, Applicants respectfully request that the Patent Office indicate as such and pass the application to issue.

Respectfully submitted,



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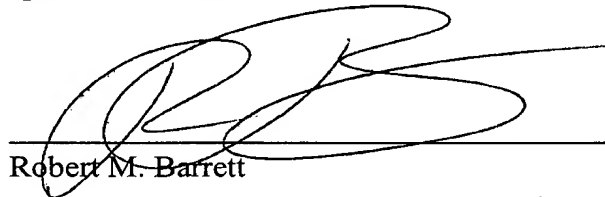
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CERTIFICATE OF MAILING

I hereby certify that this Amendment for Serial No. 09/025,363 is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to:

Assistant Commissioner of Patents  
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on July 15, 1999.

  
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